

IN THE
Supreme Court of the United States

OCTOBER TERM, 1979

No. 79-136

SIDNEY A. DIAMOND, Commissioner of
Patents and Trademarks, *Petitioner*

v.

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEAL

BRIEF OF:

Dr. Leroy E. Hood, Dr. Thomas P. Maniatis, Dr. David S. Eisenberg,
The American Society Of Biological Chemists, The Association Of
American Medical Colleges, The California Institute of Technology,
The American Council On Education As *AMICI CURIAE*.

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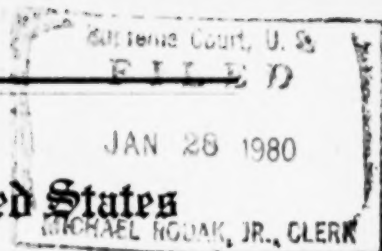
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INTEREST OF AMICI CURIAE

Amici Curiae are biochemists and molecular biologists working in university laboratories, a learned society devoted to the extension of biochemical knowledge, a university pre-eminent in scientific research, and associations of medical schools, post-secondary schools and learned societies whose members are engaged in biomedical research and delivery of health care.¹

Each of the individual Amici Curiae is engaged in research involving molecular biology. Dr. Maniatis, at the California Institute of Technology, is generally acknowledged to be one of the leaders in the field of recombinant DNA technology.² He, together with Dr. Hood, who is also at the California Institute of Technology, is using recombinant DNA techniques to produce interferon, an antiviral drug, from bacteria. Dr. Eisenberg studies the atomic structure of biological molecules. The research conducted by Amici has immediate applications in the fields of immunology and pharmacology, and long range significance for many areas of agriculture and medicine.

The American Society of Biological Chemists is a nonprofit corporation, organized under the laws of the State of New York and devoted to the extension and utilization of biochemical knowledge. The Society's 5,000 members are elected on the basis of their scientific qualifications and excellence in the fields of biochemistry and molecular biology. Members of the Society are employed by universities, research foundations, government laboratories and commercial corporations.

¹ The parties in this case have granted approval to these Amici to file this Brief. Their letters of approval have previously been filed with the Court.

² Recombinant DNA involves the transfer of genetic material from one organism to another thereby "constructing" new strains of bacteria. The extraordinary promise of this technology has led scientists to compare it in importance to the discovery of nuclear fission and fusion. *Recombinant DNA: Accelerated Processing of Patent Applications For Inventions*, 42 Fed. Reg. 2712 (1977).

Another of the Amici, the Association of American Medical Colleges, is a voluntary, non-profit corporation established under the laws of the State of Illinois, having its principal place of business in the District of Columbia. Its corporate purpose is the advancement of medical education. Its institutional membership includes virtually all (125) accredited and operating non-profit medical schools in the United States. Membership also includes over 400 teaching hospitals in which undergraduate and graduate medical education is conducted, and 68 academic and professional societies, the members of which are actively engaged in medical education and biomedical research. Together, the members of the Association and the medical colleges conduct a substantial portion of the nation's biomedical research.

The California Institute of Technology is one of the world's preeminent institutions for scientific research and its faculty and students are significantly involved in research in biochemistry and molecular biology. The Institute is a private university at which pioneering developments in space technology, radio astronomy, physics, biochemistry and recombinant DNA techniques have occurred.

The American Council on Education is a non-profit corporation organized under the laws of, and located in, the District of Columbia. Founded in 1918, the Council is a membership organization composed of 1,385 non-profit institutions of higher education from both the public and private sectors, many of which are engaged in basic research in biochemistry and molecular biology. The Council's work is financed by membership dues, by grants from foundations and learned and professional societies, and by grants from contracts with the Federal Government. Through its committees the Council has sought to foster patent policies that harmonize college and university research goals with public needs. The Council is the nation's major coordinating body in post-secondary education.

Each Amicus has a fundamental interest in the outcome of this case. Some of the Amici receive contract funds from commercial corporations whose future funding of research in this field is certain to be influenced by this Court's decision. All of the individual Amici receive or plan to receive indirect funding from royalties on patents which are held by their respective universities. The Court's decision in this case will inevitably have a substantial impact on the financing of research at academic institutions, on the way in which research in the laboratories of these Amici is financed, and on the probability that research of these Amici will be commercially developed so as to find useful, lifesaving and life-improving application.

Though engaged primarily in basic research, Amici have an interest in seeing their work reach commercial development. They fear that adoption of a *per se* rule excluding all living things from patentability will inhibit commercial development of the advances they are making in recombinant DNA research. Such inhibitions will occur because the incentive to follow through on many scientific advances, so that they will be commercially useful, will be lacking without appropriate financial incentives. For example, it is a scientific breakthrough to clone the interferon gene in a bacterium. However, to maximize the production of interferon from such a modified bacterium will require a great deal of additional scientific expertise which will not be forthcoming without the protection and rewards that patents provide to the scientific investigator and to the commercial sources which normally fund such work. Even more than in other fields of endeavor, the industrial use of microorganisms is dependent upon patent protection since the "machinery" used in this industry, newly constructed bacteria, are self-reproducing. Once a bacterium which costs millions of dollars to produce is released into the environment—e.g., dropped onto an oil spill—it can be reproduced for pennies. Thus, without the protection of a patent, the developer of a new bacterium will be hard-pressed to recoup his substantial investment.

The fact that patent protection is a prerequisite to commercial development has been clearly documented in connection with past developments in biomedical research.³ For this reason, the Department of Commerce has emphasized the need to grant patent protection to the fruits of recombinant DNA research. The Assistant Secretary of Commerce for Science and Technology stated:

"We must either preserve proprietary rights in the innovations which flow from the [recombinant DNA] research, or we must insist that the government itself undertake to do what private industry now does—bring these innovations all the way to the market place."⁴

Amici request this Court to take notice of the potential benefits to be derived from recombinant DNA technology, and the fact that denying patent protection in this case will adversely impact these potential benefits.

STATEMENT OF THE CASE

Amici Curiae consider that certain procedural aspects of this case were insufficiently underscored in Petitioner's statement and may be relevant to the Court's disposition of the

³ In 1976, the President's Biomedical Research Panel reported evidence of a clear link between the need to protect intellectual property rights and the successful transfer of research innovations to the delivery of health care. "Disclosure of Research Information," June 30, 1976, DHEW Publication No.(os) 76-513.

A GAO Report entitled "Problem Areas Affecting Usefulness of Results of Government Sponsored Research in Medicinal Chemistry" reached the same conclusion. *GAO Report*, No. B-164031. That Report found that from 1962 to 1968, industry virtually boycotted the development of drugs from new discoveries and basic research because of doubts about the availability of patent protection.

⁴ Recombinant DNA Research Act of 1977: *Hearings on H.R. 4759 and 4849 Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 241 (1977) (Statement of Betsy Ancker-Johnson).

question before it. The Patent Examiner rejected the claims in question not on the ground that they were "living organisms," but because they were products of nature (Pet. App. H, 166a-167a). This first ground was introduced *sua sponte* by the Board of Patent Appeals (Pet. App. G, 159a). The patent applicant objected to the Board relying on this previously unargued ground without a remand to the Patent Examiner for a threshold determination on this issue. The Board granted the applicant's request for reconsideration "to the extent of reconsidering our prior decision," but denied it "with respect to making any changes therein," holding as follows:

"We do not agree with appellant that our decision amounts to a new ground of rejection; on the contrary, the statutory basis for both the Examiner's rejection and our affirmance is 35 USC 101 as explained at the top of page 2 of our decision of May 20, 1976" (Pet. App. I, 168a-169a).

SUMMARY OF ARGUMENT

On the sole question before the Court—Are living things unpatentable *per se*?—we agree with the Court of Customs and Patent Appeals ("CCPA") that living organisms are not *per se* unpatentable under Section 101, 35 U.S.C. 101.⁵

Living things are ordinarily not patentable, not because they are alive, but because they are almost always "products of nature." Products of nature are not "inventions" and for that reason are excluded from the definition of patentable subject matter set forth in Section 101.

In 1930 plant hybrids were perceived to be products of nature, not inventions. The Plant Patent Act was enacted to extend patent coverage to these products of nature. Its

⁵ Amici disagree with the Commissioner and the CCPA as to the purpose of this Court's remand in light of *Parker v. Flook*, 437 U.S. 584 (1978), with their reading of the Plant Patent Act of 1930, 35 U.S.C. 161, *et seq.* and the Plant Variety Protection Act of 1970, 7 U.S.C. 2321 *et seq.*, and also with their interpretation of Section 101.

enactment does not support the inference that the Commissioner draws—that plants were unpatentable solely because they were alive. Similarly, the Plant Variety Protection Act extended patent-like protection to certain sexually reproduced plant hybrids, otherwise unpatentable as products of nature.

Thus, Congress has not impliedly expressed its will that living things be unpatentable *per se*. Assuming that the other conditions of patentability are met, new strains of bacteria constructed by the techniques of modern molecular biology are within the bounds of patentable subject matter. Although Congress in 1793, when the predecessor of Section 101 was enacted, did not have transformation or recombinant DNA in mind, Congress has expressed its intention to bestow patents upon the fruits of such new and useful technologies. Moreover, when Congress has determined that other considerations of the public interest outweigh the public interest in providing an incentive for new research, it has known how to exclude specific subject matter from patentability. *E.g.*, 42 U.S.C. 2181.

Though for reasons different from those of Petitioner, Amici disagree with the response of the CCPA to the remand of *Parker v. Bergy*, 438 U.S. 902 (1978). The CCPA took the most dramatic and least analytic view possible of this Court's remand for reconsideration in light of *Flook*. Focusing on the quotation from *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972), that there be an appropriate signal from Congress before any extension of the patent laws, the CCPA stated, "To conclude on the light *Flook* sheds on these cases, very simply . . . we find none" (Pet. App. 26a). But the CCPA was incorrect in determining that the only "launching pad for argument" (Pet. App. 20a) based on *Flook* was the *Deepsouth* cautionary language. *Flook* has a more substantial and relevant basis for decision which should have been discussed by the CCPA, but was not. *Flook* is the most recent in a line of cases, including *Gottschalk v. Benson*, 409 U.S. 63 (1972), that seeks to provide guidance concerning the scope of statutory patentability under Section 101. This line of cases, dealing with a

series of frontier developments in science and technology, seeks to ensure that laws of nature, principles of nature, phenomena of nature and products of nature are not patentable under Section 101.

The patent claims before this Court were originally rejected by the Patent Examiner on the ground that they were drawn to a product of nature—the very ground that is at the heart of *Flook*. Only because of the convoluted history of this case is that narrow issue not presented to this Court. Instead, the Court has before it the far-reaching question of whether "living organisms" are patentable subject matter.

We think that a decision on this extraordinarily broad ground is premature and, on this record, unnecessary. An adverse decision on this broad ground would severely restrict the research conducted by Amici and would have severe implications for the mix of incentives currently provided by the federal government for such research. Additionally, the living/nonliving test for patentability proposed by the Commissioner is unworkable; there is no agreement on a workable or meaningful definition of life. We urge the Court, therefore, to remand the case to the CCPA for thorough analysis and decision on the product of nature question, or to dismiss the writ of certiorari as improvidently granted. Alternatively, the decision of the CCPA should be affirmed because the definition of patentable subject matter set forth in Section 101 does not *per se* exclude all living things.

ARGUMENT

I.

GIVEN THE CURRENT RECORD, THE APPROPRIATE COURSE IS TO REMAND THE CASE OR DISMISS THE WRIT OF CERTIORARI AS IMPROVIDENTLY GRANTED

The question before the Court—Are living organisms *per se* unpatentable?—is a question of first impression. The disposition of this question will have far-reaching implications.

Economic incentives for research such as conducted by Amici will be reduced by a rule excluding all living organisms from patentability. Such a rule will adversely affect commercial development of the fruits of the research of Amici, and will also have a negative effect on the competitive stance of American industry in the extremely competitive field of biotechnology.⁶ Furthermore, such a rule would impose an unworkable test for patentability. Scientists agree that the line separating life and non-life cannot be sharply drawn; it is indefinite and even then, arbitrary.

Moreover, the procedural history of this case sets a faulty stage for deciding what is almost a theological issue. A narrower ground of decision—whether the claims at issue are unpatentable as products of nature—is not before this Court, despite the fact that the Patent Examiner relied solely on this ground. After this case was remanded to the CCPA for reconsideration in light of *Parker v. Flook*, 437 U.S. 584 (1978), the product of nature ground for rejection should have been addressed. It was not. Consideration of this question might have eliminated the need to decide if living things are *per se* unpatentable. This case should be remanded specifically for consideration of the product of nature ground. Alternatively, the writ of certiorari should be dismissed as improvidently granted.

A. In Reconsidering This Case In Light Of *Parker v. Flook*, The CCPA Should Have Examined The Product Of Nature Ground

Parker v. Flook, *supra*, is relevant to the disposition of this case because here, as in *Flook*, “the case turns entirely on the proper construction of § 101 of the Patent Act, which describes the subject matter that is eligible for patent protection.” *Id.* at

⁶ See, “Who’s Ahead, Who’s Behind,” 238 *Nature*, 123 (1980). *Nature* notes that of the biotechnological patents delivered since 1977, 124 originated in Japan and 39 in the U.S. It states: “Japan has taken an incontestable lead in biotechnology.” *Ibid.*

588. The basis for inquiry in *Flook*, as in *Gottschalk v. Benson*, 409 U.S. 63 (1972), turned on the following statement in *Benson*:

“‘A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right’. *Le Roy v. Tatham*, 14 How. 156, 175, 14 L.Ed. 367. Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” 409 U.S. at 67.

In *Flook* and in *Benson* this Court attempted to draw the line between what is properly the property of the public as a principle or product of nature, and what is patentable as an invention, *applying* a law of nature to a new and useful end. See also *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).⁷ Interpreting Section 101 to limit patentable subject matter to “inventions,” this Court has been true to an historical recognition that the “rights and welfare of the community must be fairly dealt with and effectually guarded.” *Kendall v. Winsor*, 21 How. 322, 329, 16 L.Ed. 165, 168 (1859).

Flook dealt with an algorithm for which “the line between a patentable ‘process’ and an unpatentable ‘principle’ is not always clear.” *Parker v. Flook*, *supra* at 589. This Court there stated:

“The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processess, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect. . . .

⁷ The “invention” requirement is not subsumed by Sections 102 and 103, as the CCPA contends (Pet. App. 15a). This Court has expressly rejected that position. *Parker v. Flook*, *supra* at 592-94. Thus, the tests for invention articulated in *Funk*, which predated the 1952 reorganization of the patent statutes, are pertinent to the patentability of the claims at issue. *Id.* at 591-94.

“... [T]he discovery of such a [natural] phenomenon cannot support a patent unless there is some other inventive concept in its application.” (Footnote omitted.) *Id.* at 593.

Thus, the Court’s remand should have guided the CCPA to look more closely at the line between statutorily patentable inventions, on the one hand, and discoveries of products or phenomenon of nature, on the other, particularly since in this case the patent claims were originally rejected on the ground that they were products of nature.

B. In Order That The Product Of Nature Ground May Be Fully Considered, The Case Should Be Remanded

In view of the foregoing and the unusual procedural context in which this case arises, substantial doubt is raised as to whether these claims present an appropriate vehicle for more than an advisory opinion on the fundamental question of the *per se* exclusion of living organisms from patentability under Section 101.

There is some question whether the Board of Appeals, which first introduced this question into the record, can add a ground for rejection without addressing the specific ground cited by the Patent Examiner.⁸ In its discussion of the procedural context on remand from this Court, the CCPA, with respect to *Bergy*,⁹ asserted that a new ground had been added and that

⁸ See 37 C.F.R. § 1.196(d) which provides that the Board of Appeals “normally will confine its decision to a review of rejections made by the primary examiner. . . .” If it believes another ground should be included, “the Board shall set a period, not less than one month, within which the applicant may submit to the primary examiner an appropriate amendment, or a showing of facts or reasons, or both, in order to avoid the grounds set forth in the statement of the Board of Appeals.” The record does not indicate that this procedure was followed in this case apparently because the Board of Appeals thought it was not substituting a new ground for rejection (Pet.App. I, 168a).

⁹ We recognize that the Court has remanded the *Bergy* case to the Court of Customs and Patent Appeals and has directed that it be dismissed as moot. We refer to *Bergy* here only to the extent necessary fully to explicate the case at hand.

“we have an anomalous situation here in that the Board affirmed on a *new* ground without so stating, not reaching the *sole* ground relied on by the examiner” (Pet. App. 39a). In *Chakrabarty*, the Board of Appeals asserted that it had not added a new ground for rejection (Pet. App. I, 168a), although the record clearly demonstrates that the Patent Examiner relied solely on the product of nature ground (Pet. App. H, 166a-167a).

We set forth this procedural framework to indicate the peculiarity of the case as it reaches this Court. The Commissioner has abandoned the very ground for rejection that is most relevant to the *Flook* analysis and seeks only to reverse the CCPA’s decision that living things may be patented.¹⁰ Because the Commissioner failed to assert the product of nature ground before the CCPA, there is no one with standing to press it to this Court. Amici are concerned that the Court may find itself reaching a largely abstract issue not ripe for decision because of the procedural oddities of this case.¹¹

Remanding for closer analysis of this difficult question—i.e., the proper interpretation of the product of nature limitation—is consistent with *Flook* and *Benson*, as well as with

¹⁰ In the first *Chakrabarty* CCPA decision, Judge Baldwin, dissenting, would have held that “this improvement in the utility for which the unpatentable starting material was already suited does not change the essential nature of the starting material and does not make the modified thing statutory subject matter” (Pet.App. F, 154a). Thus, Judge Baldwin would have decided the question on product of nature grounds and would have held, essentially, that the *Chakrabarty* claims were not sufficiently “modified” (Pet.App. F, 152-154a).

¹¹ Amici do not take any position as to whether *Chakrabarty*’s claims are “products of nature” as the Patent Examiner found. In any case, *Chakrabarty*’s discovery employed only first generation “transforming” techniques which are less sophisticated than classical recombinant DNA techniques, which involve complex chemical surgery to cut long threadlike DNA molecules into pieces. The resulting segments of DNA are recombined with the DNA of a suitable bacteria and then reinserted into the bacteria to propagate and function.

earlier cases reflecting this Court's analysis of the meaning of the "invention" requirement.¹²

A new remand to the CCPA for a more definitive answer to this question—even if it entails a further remand from the CCPA to the PTO¹³—is far more consistent with Section 101 and with this Court's prior decisions than would be a ruling on the abstract question as to whether "living organisms" can be patented.

C. A Living/Non-living Test For Patentability Would Be Unworkable And Scientifically Meaningless

The Commissioner proposes that future decisions as to patentability be made on the basis of whether or not the claimed invention is alive. Such a standard would be unworkable. There is no distinct line between life and non-life.

The prevailing view among scientists is that the essential characteristic of "living" matter is nothing more than its complexity. "Life is not one of the fundamental categories of the universe, like matter, energy and time but is a manifestation of certain molecular combinations." N. H. Horowitz, F. D. Drake, S. L. Miller, L. E. Orgel and C. Sagan, "The Origins of Life" from *Biology and the Future of Man*, 165 (P. Handler, Ed. 1970).

Nobel Laureate Erwin Schrodinger argues that the transition from atoms to molecules, to giant molecules such as enzymes, to simple viruses and on up to bacteria is a continuum. At some arbitrary level the aggregates take on sufficient complexity that they are regarded as living. E. Schrodinger, *What Is Life* (1958).

¹² E.g., *O'Reilly v. Morse*, 15 How. 62, 14 L.Ed. 601 (1853); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86 (1939); *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *supra*.

¹³ Katz, Examiner in Chief, dissenting in the Board of Appeals decision in the *Bergy*, case would have remanded to the Examiner for a fuller record on this issue (Pet.App. D, 139a).

Not only is the line between living and inert matter arbitrary, it is also likely to be redrawn as a result of recent research in molecular biology. For example, scientists have recently discovered an entity called 'viroid'. Viroids consists only of a closed circular chain of RNA, but are nevertheless infective and act in other ways like a living virus.¹⁴ S. E. Lauria, J. E. Darnell, Jr., D. Baltimore, Allan Campbell, *General Virology* (1978).

Thus, the living/non-living test for patentability proposed by the Commissioner is unworkable. Moreover, there is no scientific significance in the proposed test. A more workable test is to exclude products of nature from patentability. This standard, although not completely free of arbitrariness,¹⁵ is derived, at least, from the long-standing statutory requirement of "invention."

D. Alternatively, The Writ of Certiorari Should Be Dismissed As Improvidently Granted

This Court has dismissed a writ of certiorari as improvidently granted where the issue of importance was not "presented with sufficient clarity," *Kimbrough v. United States*, 364 U.S. 661 (1961), or where the fundamental question was not presented on a record "sufficiently clear and specific" to permit decision of the issues presented in the petition. *Massachusetts v. Painten*, 389 U.S. 560, 561 (1968).

The fundamental question presented to this Court—Are living things *per se* unpatentable?—is not fully developed. The implications of imposing such an arbitrary and unworkable

¹⁴ The question of whether a virus should be considered as "living" is also disputed. The accepted view is that viruses can be characterized as both "exceptionally simple microbes and as exceptionally complex chemicals." B.D. Davis, R. Dulbecco, H.N. Eisen, H.S. Ginsberg, W.B. Wood, Jr., *Microbiology* 1014 (2d Ed. 1973).

¹⁵ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *supra* at 132-35 (Frankfurter, J., dissenting).

standard have not been explored. The Patent Examiner has not been given a chance to even consider this ground. Thus, there have been no factual findings pertinent to the question before this Court.

Moreover, the preferred and more limited ground for decision, namely, whether or not the applicant's claim presented a "product of nature," was not before the CCPA. Because the Commissioner abandoned that ground after the Board's decision, the only question before this Court is whether a "living organism" is patentable under Section 101. Where an independent and narrower ground for decision is conceivably available, this Court should avoid such questions of first impression, particularly where presented on an incomplete record. Thus, if a second remand is not appropriate, the writ of certiorari should be dismissed as improvidently granted. Undoubtedly, the question will soon be brought back to this Court, but perhaps then on a complete record with all preliminary questions dispositively decided.¹⁶

We recognize that dismissal of a writ of certiorari is extraordinary and atypical. But given the record in this case, and the status of the issues before this Court, we think that such a disposition is consistent with this Court's remand of *Bergy* in light of *Parker v. Flook*.

¹⁶ An alternative disposition would be to affirm the decision of the CCPA, but with an opinion that suggests the need to look more critically, and perhaps more expansively at the definition of "product of nature." Because the Commissioner appears bound by the Board's determination that *Chakrabarty's* claim did not involve a "product of nature," that ground has not been brought before this Court. Nonetheless, an affirmance by this Court does not determine the ultimate validity of the claims at issue because of potential private actions. Appeals reaching this Court from decisions of the CCPA and the Patent Office are different from appeals in an inter partes private action, such as an action for infringement or for invalidity of the patent, in which a private litigant would undoubtedly include among the arguments the very ground for rejection relied on by the Patent Examiner in this case.

II.

IF IT IS NECESSARY TO REACH THE MERITS, THE DECISION OF THE CCPA SHOULD BE AFFIRMED

If this Court reaches the merits of the CCPA's decision below, the CCPA should be affirmed. Living organisms are not *per se* excluded from patentability.

The Commissioner argues that Congressional intent to *per se* exclude living things from patentability can be inferred from historical facts: (1) That Congress, in enacting the predecessor of Section 101, failed to include living things in its list of patentable subject matter; (2) That in 190 years the case before the Court is the first to raise the issue that living things are patentable;¹⁷ and (3) That enactment, in and of itself, of the Plant Patent Act of 1930, 35 U.S.C. 161 *et seq.*, and the Plant Variety Protection Act of 1970, 7 U.S.C. 2321 *et seq.*, demonstrates a Congressional intent to exclude all living things, with the exception of plants, from patentability.

Congress possesses the authority to bestow patents upon living things. In enacting the predecessor of Section 101 in 1793, Congress meant only to limit patentable subject matter to "new and useful inventions," and did not *per se* exclude all living things. The passage of the Plant Patent Act and the Plant Variety Protection Act do not create a contrary inference. Those acts were passed because Congress believed many plant hybrids to be "products of nature," and hence unpatentable for that reason and not because they were alive.

A. Congress Has The Constitutional Authority To Bestow Patent Protection On Living Things

There has been no contention that a patent on a living organism would be unconstitutional. The Constitution granted Congress broad authority to reward inventions and discoveries:

¹⁷ Amici do not undertake specifically to rebut this argument. Every issue must arise for the first time. Moreover, only the recent advances in biology have made it possible to create new living organisms, such as the bacteria at issue, and thus give rise to the question before the Court.

"The Congress shall have power . . . [8] To promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries; . . . And [18] To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers" *U.S. Const.* art. I, sec. 8.

The Commissioner does not dispute that this broad grant of authority empowers Congress to bestow patents upon living things. Moreover, fifty years of the Plant Patent Act demonstrate universal acceptance of the constitutionality of patents on plants. In fact, the Fifth Circuit Court of Appeals has recognized the constitutionality of the Plant Patent Act, notwithstanding the fact that it provides for the patentability of living things. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F.2d 1347, 1382 (5th Cir. 1976).

Thus, if this Court considers the broad question of the patentability of living organisms, the only issue is whether Congress exercised its authority in such a manner as to permit patents on living things, subject of course to the ordinary requirements for patentability. In other words, in enacting the predecessor of the current patent statutes, did Congress exclude from patentability all living things?

B. The Historic Breadth Of The Statutory Patentability Standard Is Inconsistent With Implied Exclusion

As the Commissioner points out (Pet. Brief at 13), the predecessor of the current Section 101 was enacted almost 190 years ago and is only slightly changed since then. That statute defined patentable subject matter as "any new and useful art, machine, manufacture, or composition of matter." Petitioner argues that the failure of Congress to include living things within its listing of patentable subject matter creates an inference that no living thing is patentable.¹⁸

¹⁸ To support this inference the Commissioner relies on this Court's holdings, in other areas, that the patent monopoly be strictly construed. But the cases relied on by the Commissioner are inapposite. In *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518,

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Petitioner's argument mocks Congressional purpose. Strictly construing the scope of patentable subject matter to exclude all things not contemplated by Congress in 1793 would undermine the entire patent system. Congress intended patents to be bestowed on *new* discoveries and inventions. In fact, patent protection is available only if the invention was not obvious to one skilled in the art. *Hotchkiss v. Greenwood*, 11 How. 248, 13 L.Ed. 683 (1851); 35 U.S.C. 103. Thus, Congress could not have expected that it had foreseen all new inventions and provided for their patentability. Rather, as this Court has previously held:

"The true policy and ends of the patent laws . . . are disclosed in that article of the Constitution, . . . viz.: 'to promote the progress of science and the useful arts,' contemplating and necessarily implying their extension, and increasing adaptation to the uses of society." *Kendall v. Winsor*, *supra*, 21 How. at 328, 16 L.Ed. at 168.

Congress did not intend to impose a static definition of patentability, limited by the fields of endeavor existing in 1793. Instead, Congress intended to grant a limited monopoly for those inventions which "serve the ends of science—push back the frontiers of chemistry, physics, and the like; and make a distinctive contribution to scientific knowledge." *Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147,

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530-31 (1972), this Court was concerned only with whether the patent laws should be given extraterritorial effect. Strict construction limiting the patent monopoly to the United States is quite different than a strict construction excluding new technologies. The 1952 Congress could foresee export of United States manufacture, but the 1793 Congress recognized that it could not foresee all technological advances.

In *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 232 (1964), the patentee was attempting to secure a monopoly on an unpatentable item by asserting rights under a State's unfair competition laws. In *Graham v. John Deere Co.*, 383 U.S. 1 (1966), the Court articulated the test for "obviousness" to be applied under Section 103. At page 7, as cited by Petitioner, this Court discussed Thomas Jefferson's aversion to monopolies, which later ripened into support for the patent system. In fact, Jefferson drafted the 1793 Patent Act. *Id.* at 10.

154 (1950) (Douglas, J., dissenting). As a recent Congress has stated, the listing in Section 101 of statutory subject matter is not restrictive, but "may include anything under the sun that is made by man." H.R. Rep. No. 1923, 82nd Cong., 2d Sess. 6 (1952); S. Rep. No. 1979, 82nd Cong., 2d Sess. 5.

Perhaps it is the Commissioner's position that living things are *per se* excluded from patentability because, in the government's view, they do not satisfy classic definitions of "machines," "manufactures" or "compositions of matter."¹⁹ Whether the Commissioner relies on this basis for excluding "living things" from patentability or on the ground that they are not inventions is unclear from the government's argument. The cases dealing with these subject matter categories demonstrate that certain living things do in fact fall within them.

Bacteria such as those constructed by techniques of recombinant DNA are clearly new compositions of matter. A patentable composition of matter results from the mixing of two or more ingredients to produce a product with different or additional properties not possessed individually by the ingredients. *P. E. Sharpless Co. v. Crawford Farms, Inc.*, 287 F. 655, 658 (2d Cir. 1923). "There is no restriction as to the nature of the composition which may be patented." *Ibid.* Recombinant DNA techniques, which break DNA chains and remove and/or insert new segments into the DNA of an existing bacterium are used to construct strains which possess properties not found in naturally occurring bacteria.

¹⁹ Amici recognize that "[t]he plain language of § 101 does not answer the question" as to the full scope of Section 101. *Parker v. Flook*, *supra* at 588. However, analysis of judicial interpretation of the four categories of invention demonstrates that new bacteria created by techniques of recombinant DNA are well within the bounds of Section 101.

Some bacteria are also manufactures. This Court has required that a manufacture differ from the raw materials used to make it by possessing "a new or distinctive form, quality, or property." *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931).²⁰ The *Pseudomonas* developed by Dr. Chakrabarty possess a new quality or property; they can decompose more than one component of crude oil, a quality possessed by no other bacterium (Pet. App. 30a-31a).²¹

Thus, Congress did not mean to exclude all living things from patentability simply by failing, in 1793, specifically to include "living" machines, manufactures, or compositions of matter within its definition of statutory subject matter. Congress did, however, impose a requirement that patents be bestowed only on "inventions." This standard excludes from patentability "[p]henomena of nature, . . . mental processes, and abstract intellectual concepts." *Gottschalk v. Benson*, *supra* at 67. As we shall see, this standard had been applied, prior to passage of the Plant Patent Act, to exclude plants from patentability under Section 101.

²⁰ The orange with borax-treated rind at issue in *Brogdex* was not patentable because it remained a product of nature; the borax treatment did not change any of its essential characteristics. Had such a change been realized, all implications of the opinion favored patentability; there was no mention of a *per se* exclusion of all living things.

²¹ Bacteria can also, by means of recombinant DNA technology, be made to produce human insulin. Bacteria occurring in nature do not possess this capacity.

A bacterium might also be characterized as a machine. In 1853 this Court understood the term "machine" to include "every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." *Corning v. Burden*, 15 How. 252, 267; 14 L.Ed. 683, 690 (1853). This term is understood today to include devices which utilize chemical and electrical processes, as well as those utilizing mechanical means. By means of chemical processes which occur inside bacteria, bacteria operate as machines to "produce a certain effect or result."

C. The Passage Of The Plant Patent Act And The Plant Variety Protection Act Does Not Support An Inference That Congress Intended Living Things To Be *Per Se* Unpatentable

The Commissioner places great reliance on certain inferences which he alleges can be drawn from the Plant Patent Act. We agree with the Commissioner that in 1930 plants were unpatentable and the Act was necessary to extend patent protection to plants. However, plants were unpatentable, not because they were alive, but for reasons related to our interpretation of Section 101. Many hybrids extended protection under the Plant Patent Act would have been considered "products of nature" under Section 101 and would therefore have been unpatentable.

Petitioner's argument that passage of the Plant Patent Act and the Plant Variety Protection Act creates an inference that Congress in 1793 intended to exclude all living things from patentability begins with the premise that the plain language of the statutes reveals this conclusion. It does not. The passage and language of the plant acts are entirely consistent with the position of Amici—that many plant hybrids were unpatentable because they were products of nature.

To support the inference he would draw, the Commissioner relies on scattered statements taken out of context from the legislative history and on a statement by Secretary of Agriculture Hyde. These statements ignore the thrust of Congressional concern.²²

²² As the principal House sponsor Representative Purnell noted, the bill presented issues "that few are competent to discuss, but the Commissioner of Patents has given this very, very careful study." 72 Cong. Rec. 8392 (1930). As we shall see, the Commissioner of Patents understood that plants were generally unpatentable because they were products of nature and not because they were alive.

Moreover, it may well be that Secretary Hyde suggested that plant hybrids were unpatentable not because they were alive, but because they were products of nature. His reference to the

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Representative Purnell, the Act's principal House sponsor, recognized that plants were not "inventions" because in most cases man merely selected a new and desirable hybrid from a field. The hybrid was created by natural processes, without man's creative invention. He carefully distinguished between "plant developers" and "industrial inventors," and recognized that the patent laws also distinguished between the two. *Hearings on H.R. 11372 Before the House Comm. on Patents*, 71st Cong., 2d Sess. 2 (1930).²³ Similarly, both the House and Senate committees distinguished between plant developers and industrial inventors, and recognized that the patent law did also.²⁴

From Congressional descriptions of the plants covered by the Plant Patent Act it is readily apparent that the great majority of newly developed hybrids were, prior to passage of

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unpatentability of living things might well have been a shorthand reference to an argument he developed more fully in the same letter upon which the Commissioner so heavily relies:

"... the words 'invented' and 'discovered' . . . shall be interpreted to include invention and discovery in the sense of finding a thing already existing and reproducing . . . ' [These words,] interpreted in the light of agricultural and horticultural experience and history, would appear to make possible the patenting . . . of any new and distinct variety wherever discovered. . . ." H.R. Rep. No. 1129, 71st Cong., 2d Sess. Appendix A (1930); S. Rep. No. 315, 71st Cong., 2d Sess. Appendix A (1930).

²³ The Petitioner, by contrast, cites a letter from Edward Rumeley, of New York City, to which he holds Representative Purnell to have concurred, because Representative Purnell read the letter into the record. The weight to be given this letter is reduced even further when one notes that Mr. Rumeley was apparently quoting from a news article. *Id.* at 4.

²⁴ "The bill will remove existing discrimination between plant developers and industrial inventors." H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930).

the Act, unpatentable products of nature.²⁵ Congress understood that man did not cause the creation of the new hybrid, he merely arranged to have nature work in his fields, where he could detect the creation of new varieties. Man's involvement was limited to assisting pollenization; in some cases, *e.g.* sports and mutants, man did nothing but recognize that the new plant which appeared in the cultivated field was useful, or otherwise distinctive. In all instances these plants were referred to as "bred" or "cultivated."²⁶

Many, if not all of these newly cultivated plants were unpatentable as products of nature under the controlling case law existing prior to 1930. For, as this Court held in 1885, patents are to be awarded only for "the creative work of . . . inventive faculty." *Hollister v. Benedict & Burnham Mfg. Co.*, 113 U.S. 59, 73 (1885). In fact, the same test for invention continues to be applied today, except in the case of plant patents. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, *supra* at 131.²⁷

²⁵ "In the first class of cases, the sports, the new and distinct variety results from bud variation and not seed variation. A plant or portion of a plant *may suddenly assume* an appearance or character distinct from that which normally characterizes the variety of species.

"In the second class of cases, the mutants, the new and distinct variety results from seedling variation *by self pollenization* of species.

"In the third class of cases, the hybrids, the new and distinct variety results from seedlings of cross pollenization of two species, two varieties, or of a species and a variety." (Emphasis added.) H.R. Rep. No. 1129, *supra* at 4; S. Rep. No. 315, *supra* at 3.

²⁶ *Hearings on H.R. 11372, supra*, at 3; H.R. Rep. No. 1129, *supra* at 1, 2, 3, 4, 5, 8, Appendix A.

²⁷ As one commentator has noted:

"Every invention which can be patented involves a discovery of some sort, but it is not every discovery that can be patented.

"The general distinction between the words is that discovery relates to phenomena, laws, or things which already existed, but which had not been perceived before, whereas invention relates to things which did not exist before." *The Law of Chemical, Metallurgical and Pharmaceutical Patents* 61 (Forman, Ed. 1967).

Before enacting the Plant Patent Act Congress considered the objection raised by Commissioner of Patents Robertson that the Constitution did not empower Congress to bestow patents on plants because plants were products of nature, not inventions.²⁸ Congressional discussion of this objection further evidences the belief of Congress that plants were then unpatentable because they were products of nature, not merely because they were alive.

Congress responded to the objection in the Reports submitted by the committees in the House and Senate. First, the broad Constitutional authority of Congress to bestow patents on "finds" not created or invented was documented.²⁹ Next, Congress expressed its belief that man was sufficiently involved

²⁸ Briefly, the Commissioner of Patents then argued that:

" . . . [I]n passing such a bill Congress may be exceeding the powers granted by the Constitution. This is particularly so with respect to the provision . . . which permits patents to be granted . . . for a 'thing already existing' . . .

"The courts have uniformly held that a valid patent can be granted only for an invention. In the case of *Thompson v. Boisselier* (114 U.S. 1) the Supreme Court of the United States said that the [patentee] . . . must be 'an inventor and he must have made a discovery,' . . .

"It may be doubted whether a valid patent can be granted for a plant even if it is a new variety, *when that plant is reproduced by operation of nature, aided only by the act of the patentee in grafting it by the usual methods.* . . ." (Emphasis added.) *Hearings on H.R. 11372, supra* at 6.

²⁹ "At the time of the adoption of the Constitution the term 'inventor' was used in two senses. In the first place the inventor was a discoverer, one who finds or finds out. In the second place an inventor was one who created something new. All the dictionaries at the time of the framing of the Constitution recognized that 'inventor' included the finder out or discoverer as well as the creator of something new. . . .

"[I]t is reasonable to suppose the framers of the Constitution attributed to the term 'inventor' the then customary meaning." H.R. Rep. No. 1129, *supra* at 8-9; S. Rep. No. 315, *supra* at 8.

in the cultivation of certain new plants so as to bring patents on those plants within Constitutional bounds.³⁰

Thus, Congress traced its path carefully so as to bestow patents on certain covered plants—theretofore products of nature—without extending beyond its constitutional authority.³¹ The Reports of both committees emphasized in closing that the Act was intended to expand the definition of invention:

“As to patents the doubt is only as to the one word, ‘inventors.’ . . . It is not to be expected that the courts would place themselves in the position of impeding the progress of the science and useful art[s] . . . by holding to so narrow a definition of the word ‘inventor’ . . .” H.R. Rep. No. 1129, *supra* at 10; S. Rep. No. 315, *supra* at 9.

³⁰ “There can be no doubt that the grant of plant patents constitutes a promotion of ‘the progress of science and useful arts’ within the meaning of the constitutional provision. The only question is, is the new variety a discovery and is the originator or discoverer an inventor?”

“There is a clear and logical distinction between the discovery of a new variety of plant and of certain inanimate things, such as a new and useful mineral. The mineral is created *wholly by nature unassisted by man*. . . . On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature *unaided by man*. . . .

“It is obvious that nature originally creates plants but it can not be denied that man often controls and directs the natural processess and produces a desired result. In such cases the part played by nature and man cannot be completely separated. . . . Nature . . . unaided by man, does not reproduce the new variety true to type.” (Emphasis added.) H.R. Rep. No. 1129, *supra* at 7; S. Rep. No. 315, *supra* at 6-7.

Petitioner also argues that by 1970 new varieties of plants were created by altering genetic structure chemically or with radiation. Changes so induced are not predictable. These techniques do nothing more than speed up nature’s own mutation processes. Thus, chemicals and radiation did not significantly alter the 1930 relationship of man and nature.

³¹ New plants found by explorers were excluded from the Act, not because they alone were unpatentable products of nature, but because such discoveries did not require the financial incentives provided by the patent system. H.R. Rep. No. 1129, *supra* at 1-2; S. Rep. No. 315, *supra* at 1-2.

With the possible exception of Secretary Hyde’s “inanimate” comment, this view of Congressional understanding and intention is wholly supported by the legislative history of the Plant Patent Act.³² Congress did not believe plants were unpatentable prior to passage of the Act simply because they were alive.

III.

A *PER SE* RULE EXCLUDING LIVING ORGANISMS FROM PATENT PROTECTION WOULD BE IMPROPER IN LIGHT OF THE ONGOING CONGRESSIONAL AND EXECUTIVE ACTIONS DIRECTED TOWARDS MAXIMIZING THE DEVELOPMENT AND APPLICATION OF DNA TECHNOLOGY

Petitioner argues that patent protection for living organisms should await “‘a clear and certain signal from Congress.’” *Parker v. Flook*, *supra* at 596. Amici do not believe that the Court must search for a “signal” in the *Deepsouth* sense, to determine whether Section 101 should be interpreted to exclude all “living organisms.”³³ But if the Court seeks such a signal, we believe that it exists in recent Congressional and executive actions pertaining to recombinant DNA.

Most of the Congressional activity in this area has been directed towards minimizing the potential safety hazards of recombinant DNA.³⁴ This inquiry has, however, taken place

³² The Plant Variety Protection Act merely extended patent-like protection to certain sexually reproduced plants. Standing alone it creates no inference that living things are *per se* unpatentable.

³³ When Congress has determined that certain subject matter should not be patented it has had no difficulty in enacting the appropriate legislation. For instance, it has determined that the incentive for invention was outweighed by other considerations of the public interest and has enacted legislation rendering inventions unpatentable to the extent they are used in the utilization of special nuclear material or atomic energy in atomic weapons. 42 U.S.C. 2181.

³⁴ See, e.g., the Recombinant DNA Research Act of 1977 (H.R. 4759; H.R. 4849; 95th Cong., 1st Sess.) and the DNA Research Act of 1977 (H.R. 3191; H.R. 3591; H.R. 3592; H.R. 5020; 95th Cong. 1st Sess.). These bills would have instructed the Secretary of Health, Education and Welfare to enact safety regulations for DNA research.

against a backdrop which assumes present patentability. *See, e.g., 2 Recombinant DNA Research: Documents Relating to NIH Guidelines for Research Involving Recombinant DNA Molecules*, DHEW Pub. No. (NIH) 78-1139 (1978) at 21. The Patent and Trademark Office itself promulgated new regulations to expedite examination of related patent applications to encourage the dissemination of information in the recombinant DNA field.³⁵ Even where restrictive legislation imposing mandatory safety standards has been proposed, *see* H.R. 3191, 95th Cong., 1st Sess. (1977), it explicitly assumes the continuation of patentability, conditioning awards on adherence to future guidelines.³⁶

Obviously, there are legitimate safety concerns, but these continue to be addressed, as they must, independent of the question of patentability. The National Institutes of Health, which has significant responsibility for financing basic biomedical research,³⁷ has enacted and recently revised guidelines governing recombinant DNA research.³⁸ Restrictions on patentability of the sort suggested here by Petitioner are totally inadequate proxies for the careful and systematic approach to safety protection being taken by the NIH and the scientific community.³⁹

³⁵ *Recombinant DNA: Accelerated Processing of Patent Applications For Inventions*, 42 Fed. Reg. 2712 (1977). These regulations were withdrawn. The practice was initiated at the request of the Assistant Secretary of Commerce for Science and Technology.

³⁶ For example, Section 6 of H.R. 3191 would have provided "notwithstanding any other law, no patent shall be granted on any procedure or organism which results from research on recombinant DNA unless all applicable guidelines have been strictly adhered to, and full and complete disclosure has been made with regard to such process or organism.

³⁷ NIH is providing approximately \$102,000,000 in grants each year for basic research in this area.

³⁸ *Recombinant DNA Research: Revised Guidelines*, 43 Fed. Reg. 60080, 60108, 60134 (1978).

³⁹ In these very cases, for example, the process claims themselves were found valid even though the product claims were not.

CONCLUSION

For the foregoing reasons, this action should be remanded to the Court of Customs and Patent Appeals or the writ of certiorari dismissed as improvidently granted. Should this Court reach the merits, the judgment of the Court of Customs and Patent Appeals should be affirmed.

January 28, 1980

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